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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,860	11/29/2001	Geert Maertens	2551-69	4135

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,860	MAERTENS ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-43* is/are pending in the application.

4a) Of the above claim(s) *17,19,27-35 and 41-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,16,18,20-26 and 36-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/553,040.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5&6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 15-43 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 15, 36 and 40 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that examiner does not indicate how Group I and Group II or III are not related in the previous Office Action.

2. Applicants argument are fully considered; However, it is not found persuasive because examiner did indicate that the group I and Group II or III are unrelated because the claimed subject matters are structurally different products (Please see line 23 on page 2 through line 3 on page 3 of previous Office Action).

3. Applicants further argue that examiner may limit the Applicants opportunity to reasonably amend the claims during the prosecution; for example, the subject matter of claim 16 is an embodiment of the subject of claim 15. The applicants respectfully submit therefore that subject matter of Group I be joined with the subject matter of Group II.

4. Applicants' argument has been respectfully considered, Group II is rejoined with Group I. Applicants are required to amend claim 15 with a defined structure of the product that is comprised in the claimed composition.

1. Regarding to rejoining the method claims of Groups IV-IX, the Applicants are reminded in the Office Action the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection is governed by 37 CFR 1.116; amendments submitted after allowance is governed by 37 CFR 1.312.

2. The following is a recitation of M.P.E.P. §821.04: Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected

invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

3. Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined . If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.

4. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

5. The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)): "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added).

6. Therefore, in accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to

maintain **dependency on the product claims** and to **include the same limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.**

7. Regarding to the argument that some of the groups of inventions should be examined together because they are felled into the same classification. This argument has been considered; however, it is not found persuasive because the criterion of restriction/election does not only depend on classification. There are many other issues other than classification should be considered regarding to the restriction requirement.

8. The requirement is still deemed proper and is therefore made FINAL.

9. Claims 15, 16, 18, 20-26, 36-39 and 40 are examined.

Specification

10. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter "E1s" in claim 20. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required.

Priority

11. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for the recitation of "E1s" in claim 20 of this application. Applicants are required to provide detail supports in lines and pages disclosed in the provisional application 60,304,194, 60,260,669 and 60,315,768. Furthermore, Applicants are also required to provide the support for the priority of claims 15-42 in both earlier domestic and foreign applications 60,304,194, 60,260,669 and 60,315,768. or patents EP98870142.1 and EP99870033.0.

12. If applicant desires priority under 35 U.S.C. 119 (e) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent

application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

13. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

14. In the case that Applicants do not provide the support disclosed by the earlier Applications or patents for claims 15-43, the priority of the claims 15-43 is considered as the filling date of parental 371 of PCT/EP99/04342, June 23, 1999.

Claim Rejections - 35 USC § 112

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with onc or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 15, 16, 18, 20-26 and 36-39 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17. Claim 15 is vague and indefinite in that the metes and bounds of claimed HCV vaccine composition are not defined.

18. M.P.E.P. 2172 recites that Although an essential purpose of the examination process is to determine whether or not the claims define an invention that is both novel and nonobvious over the prior art, another essential purpose of patent examination is to determine whether or not the claims are precise, clear, correct, and unambiguous. The uncertainties of claim scope should be removed, as much as possible, during the examination process. The inquiry during examination is patentability of the invention as applicant regards it. If the claims do not particularly point out and distinctly claim that which applicants regard as their invention, the appropriate action by the examiner is to reject the claims under 35 U.S.C. 112, second paragraph. In re Zletz, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

19. In the instant case, the claim is merely recites a function of a product, which fail to define that is the claimed product that is used for performing the claimed function. Because claim is

directed to product, the claim should comprise the structural substance rather than only a functional description.

20. M.P.E.P. further recites: If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph would be appropriate. See Morton Int 'l, Inc. v. Cardinal Chem. Co., 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993). Because HCV contains nine structural and non-structural immunogenic proteins and many immunogenic fragments, a person skill in the art cannot define what the metes and bounds of claimed product, Applicants are suggested to amend claim with a defined structural of the claimed product to overcome the rejection. This affects the dependent claims 36 and 40.

21. Claims 21, 23, 24, 25, 26, 36, 38 are vague and indefinite in that the metes and bounds of "a part thereof" are not defined. The claims are interpreted in light of the specification; however, the specification does not define what the definition of a part thereof is. If Applicants wish to claim a particular sequence structural of HCV E1 protein, please amend claimed product with a defined structure of HCVE1 protein.

22. Claims 38 and 39 are vague in that the use of a relative term of "derived". Since the specification does not provide a standard for ascertaining the requisite degree of derivation and the term of "derivation" has many interpretations, one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Therefore the claims are considered as indefinite.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

23. Claims 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

24. The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art would undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Whether undue experimentation is required is not based upon a single factor but rather a conclusion reached by weighting many factors. Theses factors were outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in re Wands, 8USPQ2d 1400 (Fed. Cir. 1988). These factors include the following:

25. 1) & 2) State of art and unpredictability of the filed. HCV vaccine has been studied with several HCV encoded proteins, such as the envelope glycoprotein E1, E2, nucleocapsid protein C, non-structural protein NS3, NS4, and NS5 and combination thereof. However, none of them is approved as a HCV vaccine so far as evidenced by Liang et al. (Annual of internal Medicine 2000, Vol. 132, No. 4, pp. 296-305). They indicate that development of HCV vaccine is extremely unpredictable because the following problems: (1) HCV virus is characterized with quasi-species due to a high rate of mutation in the hypervariable region of the envelope proteins; (2) the hypervariable region of envelope proteins contains a principal neutralization epitope responsible for inducing the neutralizing antibody; (3) the neutralizing antibody of HCV E1 or E2 develops slowly and achieves only modest titers during primary infection and tends to be a short-lived antibodies. Consequently, it emerges too late to prevent HCV infection; (4) the immunologic responses that correlate with the HCV protection and disease progression have not been clearly defined. Even with accepted animal model chimpanzees, it has been demonstrated that challenge vaccinated chimpanzees with a homologous or heterologous strain of HCV resulted in re-infection, suggesting an absence of protective immunity after natural infection; (5) Studies have shown that a vigorous multispecific cellular immune response involves in the HCV infection and an ideal HCV vaccine should not only elicit high-titer, long-lasting, and broadly directed anti-envelope antibodies but also a vigorous, multispecific cellular immune response. In particular, conserved T-cell epitopes in the core, NS3, and NS4 regions should be targeted.

26. In particularly, the expertise in the field commented the uncertainty of using the E1 as vaccine and therapeutic component done and published by inventor; Dr. Meartens et al (See Ghany et al. Hepatology 2003, Vol. 38, pp. 1289-1296). They pointed out that the accepted parameter for an improvement of a disease by a therapy is defined as resolution of symptoms or

elimination of the cause of disease. In chronic hepatitis C, viral clearance, serum amino-transferase level (typically ALT) reduction and liver histology are used for assessing a treatment response. However, they commented that no patients receiving the claimed composition achieved viral clearance and improvement of liver function as demonstrated by the reduction of ALT level after a long time observation. They also questioned about that the improved histology results because the investigation did not include the rebiopsy the placeto group. Therefore, they concluded " present we cannot recommend the use of this strategy either as initial therapy for untreated patients or maintenance therapy for relapsers or nonresponders to piginterefon and ribavirin (See entire document).

27. 3) &4). Number of working examples and amount of guidance. The specification only presents that use of HCV envelope protein produced by mammalian cell or yeast is able to induce an immune response, predominantly a humoral immune response in human and in chimpanzees, wherein the best results from chimpanzees model is to reduce the severity of the acute phase of HCV infection. However, there is no challenging experiment demonstrating that the claimed HCV E1 is able to induce a protective immune response that prevents HCV infection. The specification even discloses that the use of E1 is hardly to get any cellular response even when a powerful adjuvant is used (See lines 22-28 on page 58 and lines 2-5 on page 59).

28. 5) Scope of the claims. The claims broad on read on a HCV vaccine comprising HCV envelope protein E1 or any part thereof because the specification defines the therapeutic vaccine as a HCV vaccine composition that is used for the treatment, in which the vaccine is an immunogenic composition capable of eliciting protection against HCV, whether partial or complete (See lines 8-12 on page 9).

29. 6) & 7) Level of skill and nature of the invention. The invention involves one of the most complex and unpredictable field. The level of the skill in art is very high. As noted by some of the preeminent researchers on HCV, significant hurdles remain to be overcome in order for the skilled artisan to practice successful a HCV vaccine.

30. Given the above analysis of the factors, which the courts have determined, are critical in asserting whether a claimed invention is enabled, it must be considered that the skilled artisan

would have had to conduct undue and excessive experimentation in order to practice the claimed invention.

Double Patenting

31. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

32. Claims 15, 16, 18, 21-26 and 36-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16 and 21 of U.S. Patent No. 6, 635,257 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of major component of claimed composition disclosed in the patent No. 6, 635,257 B1 overlaps with the scope of claimed invention of instant application.

33. For example, claimed invention of current application is directed to a HCV vaccine composition that can be used for treating HCV infection in human, wherein the composition is made by HCV E1 proteins, in which the cysteines of said HCV envelope protein or part of thereof are blocked. The envelope protein can also be expressed as a viral like particle and formulated with a pharmaceutical accepted carrier, and adjuvant or vehicle.

34. The patent "257B1" is also directed to an oligomeric particle or a composition used as a HCV vaccine composition, wherein the major component of the composition is HIV E1 further comprising an excipient diluent, carrier or adjuvant, wherein the at least one cysteine of said HCV envelope protein or part of thereof is blocked by alkylation (Claims 1, 16, 19 and 21).

35. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the cited reference and use the claimed composition as a therapeutic composition for inducing the same immune response absence unexpected result.

36. Claims 15, 16, 18, 20-26, 36-39 and 40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 5, 6, 7, 9, 10, 11, 12, 13 and 14 of copending Application No. 09/995,791. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scopes of the claimed inventions are overlapping each other.

37. The Application "09/995,791" is also directed to a composition comprising an oligomeric E1 or the oligomerized E1 particle, which further comprises an excipient diluent, carrier or adjuvant, wherein the composition is used for induce an immune response for treating HCV infection in human (See claims 1, 2, 3, 5, 6, 7, 9, 10, 11, 12, 13 and 14).

38. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

39. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

40. Claims 15, 16, 18, 21-26, 36-39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Maertens et al. (WO 96/04385A2).

41. Maertens et al. disclosed a composition comprising purified recombinant HCV oligmeric recombinant envelope protein selected from the group consisting of E1 and/or E2 or E1/E2

expressed by mammalian cell or yeast, wherein both E1 and E2 glycosylation sites can be mutated to increase the immunogenicity (See pages 58-62). The composition further comprises a pharmaceutical acceptable adjuvant used as a medicament or vaccine for immunizing human against HCV infection (see claims 11, 36, 37, 38 and 39). Therefore, claimed invention is anticipated by the reference.

42. Claims 15, 16, 18 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Choo et al. (P.N.A.S. USA, 1994, Vol. 91, pp. 1294-1298).

43. Choo et al. discloses that administration of a composition comprising a recombinant HCV envelope glycoprotein E1 and an adjuvant into Chimpanzee animals induces a humoral immune response and get a partial protection conferred by the HCV-1 vaccine against the heterologous clinical isolate of HCV infection (See pages 1295-1296). Therefore, the claimed invention is anticipated by the cited reference.

44. Claims 15, 16, 18 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Houghton et al. (Prospects for prophylactic and therapeutic hepatitis C virus vaccines. Princess Takamatsa Symp. 1995, Vol. 25, pp. 237-243).

45. Houghton et al. discloses that administration of a composition comprising a recombinant HCV envelope glycoprotein E1 expressed by Hela cells into Chimpanzee animals induces a humoral immune response and get a partial protection conferred by the HCV-1 vaccine against the heterologous clinical isolated HCV infection (See pages 239-240). Therefore, the claimed invention is anticipated by the cited reference.

46. Claims 15, 16, 18 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Houghton et al. (Procedding of IX Triennial International Symposium on viral hepatitis and liver disease, Rizetto Purcell, gerin, Verme, eds, Edizioni Minerva Medica, Italy, 1997, pp. 656-657).

47. Houghton et al. discloses that administration of a subunit HCV vaccine comprising a recombinant HCV envelope glycoprotein E1/E2 expressed by Hela cells into Chimpanzee animals. Four out of six immunized chimpanzees get a complete protection and two out of six chimpanzees produce a less severe acute hepatitis (See pages 657). Therefore, the claimed invention is anticipated by the cited reference.

48. Claims 15, 16, 18, 36 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Weiner et al. (US Patent No. 5,670,152A).

49. Weiner et al. disclosed an immunogenic composition comprising purified HCV envelope polypeptide derived from distinct HCV isolates including HCV group I and HCV group III (See claims 1-9), wherein the composition is disclosed for using as a vaccine as well as therapeutic composition for treating HCV infection (See lines 6-19 on col. 28). Therefore, claimed invention is anticipated by the reference.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li
January 05, 2003

James C. Housel
JAMES HOUSEL 1/12/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600